

MAY 14 2009

Appl. No.: 10/522,889

Amdt. Dated Mar. 19, 2009

Notification May 15, 2009, Re: Response Mar. 19, 2009 to FOA of Sep. 19, 2008

Listing of Claim 1:

1. (As amended on March 19, 2009): A tubular liner for insertion into a duct, comprising first and second ends and a synclastic lumen formed from an auxetic plurality of adjacent polygons, said adjacent polygons connected symmetrically by a common element material, said first and second ends being open such that fluid flow can occurs through said lumen from said first end to said second end.

Remarks/Points for Discussion:

Another particular advantage of the tubular liners of the present invention further to that discussed at page 5 of Applicant's response of March 19, lines 9-16, is that they may be inverted by virtue of their being auxetic. Thus, the auxetic tubular liners of the present invention can be inserted into a duct in a compressed, and hence narrower, state (see page 22, lines 22-23) with the aid of a catheter, such that the stent can be inserted whilst inverting. Expansion of the stent after it is inserted into the vessel, allows removal of the catheter. The expansion of the stent after insertion also results in a release of energy to the plaque (or other blockage) when it is contacted by the inverted stent, thus advantageously affecting dilation of the plaque (see pages 18-20 and Figs. 5-7).

In September 2006 Applicant had received advice from the US attorney relating to amendment of the application so as to establish novelty over US 6,368,355 (Uflacker), see Information Disclosure Statement by Applicant filed on 2005-08-18.

The US attorney at the time had recommended amendments of claim 1 so as to emphasise the synclastic property of the stent, because the specification teaches that this synclastic effect is exploited by allowing inversion of the stent as it is delivered. The US attorney was of the view that the specification fully supports this concept, and therefore no amendments to the specification would be required.

Since requesting the advice of the US attorney in respect of US 6,368,355, mathematical analysis carried out for the Applicant by an independent third party illustrated that the key to the invertability of the tubular liner is the relative lengths of the elements that make up the hexagons. However, claim 1 as amended by the US attorney in 2006, which emphasizes the synclastic property of the tubular liner, appears to have a similar meaning to amended claim 1 that had been proposed to the European Patent Office, in which the tubular liner is defined to be invertible.

Whereas there is no disclosure of an invertible auxetic tube in US 6,368,355, analysis of the tubing disclosed by Uflacker determined that this tubing cannot be inverted because of differences in relative lengths of the above mentioned elements between his stent and as disclosed in Fig.'s of the current application. This is essentially because Uflacker's hexagons contain 'zigzag' elements whose length exceeds half of that of the longitudinal connecting elements, which limits the degree to which these hexagons can be compressed to achieve smaller stent diameters.

Whereas it is a general teaching of the current application that the tubing comprises hexagons, it is also disclosed in the specification that the tubing may be invertible. Consequently, it is clear that it is the dimensions of the hexagons that must be adapted to make the tubing invertible. Based on the above mentioned mathematical analysis and arguments presented, the European Patent Office confirmed their decision to grant the patent in November 2008.